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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE CONNETICS SECURITIES LITIGATION

Case No. C 07-02940 SI

REPLY MEMORANDUM IN SUPPORT OF REQUEST FOR JUDICIAL NOTICE BY DEFENDANTS CONNETICS CORP., JOHN L. HIGGINS, LINCOLN KROCHMAL, C. GREGORY VONTZ, AND THOMAS G. WIGGANS

Date: August 15, 2008
Time: 9:00 a.m.
Dept: Courtroom 10
Judge: Honorable Susan Illston

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I. INTRODUCTION

Plaintiff admits that the Court may take judicial notice of all but two of the 52 exhibits submitted by Connetics in support of its motion to dismiss. Opp. RJN at 1-2.[1] Although plaintiff admits the other exhibits are proper subjects of judicial notice, plaintiff argues that the Court should disregard 21 of those exhibits because plaintiff asserts in a conclusory fashion that the documents are "disputed." Opp. RJN at 5. That is not the law. As this Court previously held, and as the Supreme Court made clear in *Tellabs*, a court ***must*** consider "the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and ***matters of which a court may take judicial notice***." *Tellabs v. Makor Issues & Rights Ltd.*, 127 S. Ct. 2499, 2509 (2007) (emphasis added); *see also* Order at 6; *In re CV Therapeutics, Inc. Sec. Litig.*, 2004 WL 1753251, at *4 (N.D. Cal. Aug. 5, 2004). In addition, *Tellabs* instructs that "in determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court ***must*** take into account plausible opposing inferences." 127 S. Ct. at 2509 (emphasis added). When undertaking this "inherently comparative" inquiry, a court must weigh competing inferences and determine whether plaintiff has met its burden of pleading a "cogent and compelling" inference of scienter, which is an inference that is "more than merely plausible or reasonable." *Id.* at 2504-05, 2510.

Plaintiff's argument would foreclose the very analysis that is compelled by the Reform Act and *Tellabs*. Whereas the Reform Act and *Tellabs* require a court to consider judicially noticeable facts and draw inferences from those facts that are favorable to the defendants, plaintiff argues that this Court should disregard such facts whenever plaintiff disagrees with (*i.e.*, "disputes") those inferences. Opp. RJN at 1, 5. If accepted, the Court would be left with nothing to consider but the "facts" plaintiff selectively highlights and the inferences that plaintiff urges. That is precisely the legal standard that the Reform Act and *Tellabs* rejected. Moreover, the Reform Act is clear that a plaintiff cannot allege a securities fraud claim merely by stating in a

[1] The two exhibits to which plaintiff objects are summary exhibits which present accurate summaries of other voluminous and judicially noticeable facts. Exs. 49-50. Such summary exhibits are proper subjects of judicial notice and there is no legitimate reason to ignore them. *See* Fed. R. Evid. 1006 (allowing summaries of voluminous documents); *see also infra* at 12-13.

conclusory fashion, as plaintiff does here, that a statement or fact is "false" or "disputed." Rather, a plaintiff must plead facts with particularity demonstrating the reasons why the statement or fact is false. 15 U.S.C. § 78u-4(b)(1); *In re Silicon Graphics Inc., Sec. Litig.*, 183 F.3d 970, 984 (9th Cir. 1999) ("[W]e read the statutory command that a plaintiff plead all the 'facts' with 'particularity' to mean that a plaintiff must provide a list of all relevant circumstances in great detail").

Plaintiff is also wrong when it contends that the Court cannot consider the documents at issue for the truth. Opp. RJN at 1, 5. As plaintiff acknowledges, this proposition is directly contradicted by this Court's decision in *CV Therapeutics*. Opp. RJN at 5, n.1. There, the Court rejected a "plaintiffs' [argument] that the Court cannot consider any documents for the 'truth of their contents,'" holding that "[t]he Court does not restrict its taking of judicial notice in this way." 2004 WL 1753251, at *12; *see also* Fed. R. Evid. 803(8) (public records are not hearsay and may be considered for truth). In any event, even if the Court does not consider the documents at issue for the truth, the Court must consider the documents when determining whether plaintiff has pleaded a "cogent and compelling" inference of scienter. If the contents of a judicially noticeable document or a document cited in the complaint refutes an inference of scienter, the Court ***must*** consider that document and dismiss plaintiff's complaint. *See Tellabs,* 127 S. Ct. at 2509-10 (requiring court to examine judicially noticeable documents and documents incorporated by reference and to engage in comparative analysis that credits inferences favorable to defendants); *Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002) (holding that court "must consider . . . inferences unfavorable to the plaintiffs" and dismissing complaint where allegations negated a strong inference of scienter); *In re Applied Micro Circuits Corp. Sec. Litig.*, 2002 U.S. Dist. LEXIS 22403, at *12 (S.D. Cal. Oct. 3, 2002) (holding that court must consider entire contents of SEC filings selectively quoted in complaint for purpose of drawing inferences relating to plaintiff's allegations).

II. THE COURT SHOULD TAKE JUDICIAL NOTICE OF SEC FILINGS REFERENCED IN THE COMPLAINT

As plaintiff acknowledges, the Court may take judicial notice of Exhibits 6, 7, 8, 10, 12 and 13 – all of which are SEC filings referenced in the complaint. Opp. RJN at 5. Plaintiff also acknowledges that the Court may consider the documents for "the purpose of determining what the documents state." *Id.*[2] Yet, plaintiff urges the Court to refuse to consider the "truth" of, or any inferences that may be drawn from the statements contained in the documents, simply because they are "contrary" to plaintiff's allegations. *Id.* at 6. As this Court has recognized, in taking judicial notice of SEC filings, the Court is not limited to considering plaintiff's self-serving characterizations of those filings. *See CV Therapeutics*, 2004 WL 1753251, at *4. Rather, the court can and must consider the entirety of the documents to determine whether plaintiff has pleaded a strong inference of scienter sufficient to state a claim for securities fraud. *Tellabs*, 127 S. Ct. at 2509-10; *In re Wet Seal, Inc. Sec. Litig.*, 518 F. Supp. 2d 1148, 1157-58 (C.D. Cal. 2007). Likewise, *Tellabs* requires the Court to consider plausible opposing inferences that may be drawn from the whole of the documents. 127 S. Ct. at 2509-10.

Exhibit 7. Plaintiff does not allege in its complaint that Exhibit 7 – a July 25, 2006 Form 10-K/A SEC filing – contains any false or misleading statements. In fact, plaintiff repeatedly cites that filing for the truth. SAC ¶¶ 185-192. Moreover, that Form 10-K/A was issued ***after*** the end of the class period and thus cannot form the basis of plaintiff's fraud claim. SAC ¶ 346 (class period ends on July 9, 2006); *see also In re Invision Techs., Inc. Sec. Litig.*, 2006 WL 538752, at *2 (N.D. Cal. Jan. 24, 2006); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1223 n.6 (S.D. Cal. 2001). Given the express allegations in the complaint, plaintiff cannot conceivably argue (as it now attempts to do in its brief) that the Form 10-K/A contains "false" factual assertions. *See* Opp. RJN at 6. In any event, there is no allegation in the complaint that disputes

[2] Plaintiff's reliance on *Perretta v. Prometheus Dev. Co.*, 2006 WL 463533, at *5 (N.D. Cal. Feb. 24, 2006) is misplaced. In *Perretta*, the court considered the substance of the statements contained in the SEC filings in holding that plaintiff had failed to allege an actionable misrepresentation. For example, the court emphasized that the "proxy materials also disclosed a rationale for conducting the merger … Plaintiffs have at most identified a disagreement with that rationale, not how the reasoning was fraudulent." *Id.* at *7.

the fact that "until December 2005 the [inventory] reports [received from Connetics' distributors] contained inaccuracies and inconsistencies that made them unreliable." Ex. 7, at 31; SAC ¶¶ 157-176.

Exhibit 8. Plaintiff likewise does not assert that Exhibit 8 – a May 14, 2002 press release from Connetics – contains any false or misleading statements. SAC ¶¶ 84-126; *see also id*. ¶ 74. (quoting press release). There is absolutely no allegation in the complaint that the statement that "clinical studies in more than 700 patients in Europe … have shown Velac gel to be safe and effective as leading topical treatments" was either false or misleading. *See* Ex. 8; SAC ¶¶ 84-126. In fact, those statements were made before the class period and thus could not form the basis of any claim. Moreover, the European clinical tests showing that Velac was safe for humans and the approval of Velac for commercial sale in Europe (Ex. 6, at 6 and Ex. 7, at 10) are highly relevant in assessing whether plaintiff has alleged a "cogent and compelling" case that defendants in fact knew that Velac would never be approved. *See Invision Techs.*, 2006 WL 538752, at *2 n.1 (statements outside class period are not actionable but considered only in context of demonstrating "truth or falsity of Class Period statements"); *DeMarco*, 149 F. Supp. 2d at 1223 n.6 (statements before the class period "may have evidentiary relevance to the issue of scienter"); *Oppenheim Pramerica Asset Mgmt. S.A.R.L. v. Encysive Pharms., Inc.*, 2007 WL 2720074, at *5 (S.D. Tex. Sep. 18, 2007) (approval in Europe supports belief that "the FDA application would similarly be approved"); *In re Astrazeneca Sec. Litig.*, 2008 WL 2332325, at *17 (S.D.N.Y. June 3, 2008) (approval in Europe "made it not unreasonable for defendants to believe in their product"). In fact, these European clinical test results are consistent with the results of the Phase III clinical trials in the United States which involved testing on 2,200 patients. SAC ¶¶ 62, 77-81, 250; Ex. 6, at 6 and Ex. 7, at 10. Thus, the prior clinical studies in Europe, like the Phase III clinical trials in the United States, are relevant to the scienter of defendants. Those tests demonstrate that defendants had compelling reasons to be optimistic that Velac was safe and effective.

Exhibits 6, 10, 12 and 13. Plaintiff fails to allege with any specificity that any statement contained or relied on in Exhibits 6, 10, 12 and 13 was either false or misleading. SAC ¶¶ 80-81,

250-251, 226, 233, 240-245. Instead, plaintiff block quotes from these press releases and SEC filings and generically *alleges* that these statements were "materially false and misleading." *Id.* This type of "puzzle pleading" is not sufficient to plead securities fraud under the Reform Act. 15 U.S.C. § 78u-4(b)(1)(B); *see also In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1075 (N.D. Cal. 2001) (this type of pleading "obfuscates rather than clarifies" and fails to "divine precisely which statements (or portion of statements) are alleged to be false or misleading, and the reason or reasons why each statement is false or misleading") (quotation omitted). In any case, under *Tellabs*, the Court must take judicial notice of these press releases and consider them for the purpose of evaluating the statements in context and whether plaintiff has plead particularized facts creating a cogent and compelling inference of scienter. In fact, there is nothing in the complaint that disputes any of the following:

- European clinical studies involving more than 700 patients demonstrated Velac was safe and effective. Ex. 8.
- Velac was approved in Europe. Ex. 10.
- The excellent results of the Phase III clinical trials. Ex. 10.
- That "nothing in [the] clinical trials indicated the mouse study was predictive of human results." Ex. 7, at 10.
- The expert panel concluded that the positive result in the mouse study was a result of a limitation in the model, *i.e.*, it was a false positive. Ex. 1, at 5.
- Connetics submitted an NDA application for Velac to the FDA in August 2004, which was accepted in October 2004. Ex. 12.
- There is a user fee associated with an NDA application. Ex. 6, at 6.
- Connetics paid $3.5 million to Yamanouchi Europe B.V. in conjunction with its submission of the Velac NDA to the FDA. Exs. 6, 12, 13.
- Connetics began preparing its commercial operations for the launch of Velac in 2004, including, for example, hiring more than 60 new sales professionals in January 2005 as part of the sales force expansion. *See* Exs. 12, 13.

The Court must take judicial notice of these facts and must draw inferences from them, including the reasonable inference that the Phase III trials demonstrated Velac was safe and effective and Connetics incurred substantial expenses in seeking FDA approval for Velac and preparing to launch Velac. Far from supporting an inference of fraud, these facts demonstrate

that defendants actually believed that Velac would obtain FDA approval. *See Tellabs*, 127 S. Ct. at 2510; *see also In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1118 (9th Cir. 1989) (scienter dispelled by efforts to prepare product for launch).

III. THE COURT SHOULD TAKE JUDICIAL NOTICE OF FDA RECORDS

Plaintiff objects to Exhibits 30 to 43, public records evidencing the FDA's regulatory decisions and published on the FDA's website. However, plaintiff fails to articulate any reason why the Court should not take judicial notice of these records under Rule 201. Exhibits 30 to 43 are neither subject to reasonable dispute nor can their accuracy be questioned. The law is clear that courts routinely take notice of records and reports of administrative bodies, such as the FDA. *See Interstate Natural Gas Co. v. Southern Cal. Gas Co.*, 209 F.2d 380, 384-85 (9th Cir. 1953) (taking judicial notice of contract and rates filed with federal agency); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003) (taking judicial notice of FDA report posted on FDA website).

In accord with the controlling precedent, this Court has already taken judicial notice of "the fact that BenzaClin is labeled as having been shown to be a tumor promoter and having induced tumors in transgenic mice." Order at 14 n.5 (citing *CV Therapeutics*, 2004 WL 1753251, at *4); *see also, Wet Seal*, 518 F. Supp. 2d at 1157-58 ("courts regularly accept that facts in such documents may properly be considered substantively, where plaintiffs rely on the same documents and they are central to the allegations of intent to defraud."). Underscoring the relevance of BenzaClin's approval, the Court held: "defendants were aware of another drug that had been approved by the FDA despite a positive transgenic test. Thus, statements predicting that the FDA would approve Velac were not made in the face of actual knowledge that Velac could never be approved; rather, they may have been made in the optimistic belief that the transgenic testing problem was a surmountable barrier to FDA approval." Order at 14 (reference omitted).

Plaintiff simply ignores this Court's prior holding, and then wrongly contends that the court cannot take judicial notice of Exhibits 30 through 43 because they are "irrelevant" to plaintiff's claim or because plaintiff "vigorously disputes" the facts contained therein. Opp. RJN at 11. There is no reason for this Court to reconsider its prior holding. The gravamen of

plaintiff's claim is that defendants made optimistic statements about Velac's prospect for approval when, according to plaintiff, they knew all along that approval could not be obtained by the PDUFA date. The FDA records establish that defendants reasonably believed that Velac would be approved by the PDUFA date despite the results of the Tg.AC mouse study.

For example, Exhibit 32, the FDA approved label for Duac (which contains Benzoyl peroxide), provides:

> ***DUAC Topical Gel***
> ***(clindamycin, 1% - benzoyl peroxide, 5%)***
>
> For Dermatological Use Only.
> Not for Ophthalmic Use.
>
> **Rx Only**
>
> **DESCRIPTION**
> DUAC Topical Gel contains clindamycin phosphate, (7(S)-chloro-7-deoxylincomycin-2-phosphate), equivalent to 1% clindamycin, and 5% benzoyl peroxide.
>
> . . .
>
> **Carcinogenesis, Mutagenesis, Impairment of Fertility:** Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. The clinical significance of this is unknown.
>
> Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced squamous cell skin tumors in transgenic TgAC mice in a study using 20 weeks of topical treatment.

And, Exhibit 34, the approval letter for Duac, provides:

> We remind you of your postmarketing study commitments in your submission dated August 20, 2002. These commitments are listed below.
>
> 1. The Applicant commits to performing dermal carcinogenicity testing of the combination drug product.
>
> Commitment Category: NON-CLINICAL TOXICOLOGY
>
> | | |
> |---|---|
> | Protocol Submission: | Within 4 months of the date of this letter |
> | Study Start: | Within 6 months of the date of the approval of the protocol |
> | Final Report Submission: | Within 12 months after the study completion |
>
> 2. The Applicant commits to a study to evaluate the effects of the drug products on UV-induced skin cancers.
>
> Commitment Category: NON-CLINICAL TOXICOLOGY
>
> | | |
> |---|---|
> | Protocol Submission: | Within 4 months of the date of this letter |
> | Study Start: | Within 6 months of the date of the approval of the protocol |
> | Final Report Submission: | Within 12 months after the study completion |

The FDA-approved label for BenzaClin, a drug which plaintiff specifically references in the SAC at paragraph 123, also states that "benzoyl peroxide … induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment." Ex. 30, at 6. Similarly, the approval letter for BenzaClin states:

> You have agreed to submit the following protocols within 9 months of the approval of this application: … To conduct a dermal carcinogenicity study and a study on the effects of UV-induced skin carcinogenicity. These studies should be completed and submitted within 4 years of the approval of this application.

Ex. 31, at 1-2 (emphasis added).[3] These FDA public records demonstrate that dermal products that include benzoyl peroxide have been approved by the FDA despite adverse Tg.AC test results. Far from foreclosing the possibility of FDA approval, the FDA approved Duac and BenzaClin requiring only that the Tg.AC test results be included as part of the respective labels and that the companies conduct ***post-approval*** Phase IV testing.

[3] As demonstrated by the face of these documents, plaintiff's assertion that the FDA approval letters for Duac and BenzaClin, respectively, "demonstrate that the FDA required [only] post-approval testing of the effects of the drug on UV-induced skin cancers" is plainly wrong. Opp. RJN at 12-13.

Other courts have taken judicial notice of similar records and held that they are highly relevant in evaluating whether a plaintiff has met its burden of pleading a strong inference of scienter. For example, in *In re Vertex Pharms. Inc. Sec. Litig.*, the plaintiff alleged that defendants misrepresented the prospects for a drug's approval and made false and misleading statements regarding the results of Phase I and II clinical studies because the defendants failed to disclose that preclinical animal tests showed that the drug was "dangerously toxic." The court dismissed plaintiff's complaint:

> [T]he allegation that the defendants were aware that preclinical testing demonstrated a toxicity problem with VX-745 by March of 1999 is not in itself sufficient to demonstrate scienter. The fact that a drug has a certain toxicity level does not necessarily doom the drug's commercial prospects. As defendants point out, many drugs currently on the market are toxic depending on dosage levels and concentrations. Defendants note that other drugs (such as Lipitor and Zocor) have been found in animal studies to have toxic effects on the CNS in certain dosages, yet have been approved by the FDA. *See Def.'s Exh.* I, J. Thus, defendants' knowledge of some toxicity in VX-745 in 1999, without more, is insufficient to indicate "a mental state embracing intent to deceive, manipulate, or defraud."

357 F. Supp. 2d 343, 352 (D. Mass. 2005) (case citation omitted). The same analysis applies here. The fact that Velac showed a positive response in the Tg.AC model did not "doom the drug's commercial prospects." *Id.* As shown by the FDA public records relating to BenzaClin, Duac, Differin, Retin-A, Protopic, Aldara and Clobex, other dermal products have shown a positive result in animal carcinogenicity tests but were nonetheless approved by the FDA. As such, the FDA documents are exactly the type of judicially noticeable records that the Court is required to consider under *Tellabs* because they refute an inference of scienter.

Plaintiff is also wrong when it argues that the Court should not consider the contents of Exhibits 30 through 43 because defendants were not "aware" of the other drugs. Opp. RJN at 11-12. In fact, the complaint quotes at length from documents that demonstrate that (1) defendants were aware that the FDA had approved other products, including benzoyl peroxide, even though they "induced skin tumors in transgenic Tg.AC mice or had other positive findings" and (2) defendants relied on those FDA decisions when they determined that Velac would be approved. For example, the complaint specifically calls out, quotes from, and relies on

Connetics' April 26, 2005 conference call regarding the Tg.AC mouse study. *See* SAC ¶¶ 263-267. During that conference call, Connetics specifically referred to drugs such as BenzaClin that also have had positive Tg.AC test results to explain why they believed Velac would be approved. Ex. 1, at 6, 24. In any event, the FDA's approval of other drugs that tested positive in animal carcinogenicity tests demonstrates that plaintiff is simply wrong when it says that the FDA would not approve a drug that tested positive in a Tg.AC study.

Moreover, the law is clear that the court can take judicial notice of FDA public records in a securities fraud case because such records are available to and relied upon by the investing public and provide context for plaintiff's allegations. *See Vertex Pharms.,* 357 F. Supp. 2d at 352 n.4 (taking judicial notice of FDA public records); *In re Guidant Corp. Sec. Litig.*, 2004 WL 2538374, at *9 n.20 (S.D. Ind. Nov. 8, 2004) (same); *Benak v. Alliance Capital Mgmt.* L.P., 349 F. Supp. 2d 882, 889 n.8 (D.N.J. 2004), *aff'd*, 435 F.3d 396 (3d Cir. 2006) (taking judicial notice of relevant publicly available documents, charging plaintiff with knowledge thereof, and refusing to "cherry-pick" the public information helpful to the plaintiff); *Wet Seal,* 518 F. Supp. 2d at 1159 (taking judicial notice of documents to show availability of information to the market). Notably, plaintiff does not dispute that the Court can take judicial notice of similar documents under the same legal doctrine, including the FDA's Manual of Policies and Procedures (Exhibits 26 and 27) and various analyst reports (Exhibits 45 through 47). Given the lack of any objection to such documents, it is clear that plaintiff's objections here are not based on principle, but on a thinly cloaked desire to distract the Court from considering public records that are devastating to plaintiff's allegations of fraud.

Plaintiff also attempts to distract the Court from the import of the FDA public records by arguing that the facts relating to the approval of the drugs are "vigorously disputed" or because

"each drug works differently."[4] Opp. RJN at 10-11. However, plaintiff never explains what exactly it disputes about those facts, nor does it make any allegations in its complaint demonstrating with the requisite particularity that defendants misrepresented those facts. For instance, plaintiff does not allege – nor could it – that dermal products with benzoyl peroxide were not approved by the FDA despite the fact that benzoyl peroxide "induced skin tumors in transgenic Tg.AC mice." Plaintiff also does not allege – nor could it – that defendants were unaware of the FDA's decisions to approve these and other products and that defendants did not rely on those decisions when they projected that Velac would be approved. Nor does plaintiff allege that any additional carcinogenicity testing was required before the drugs were approved. Further, the labels for these drugs make clear that, like Velac, each is a topical treatment for a dermatological condition.[5] At bottom, plaintiff's quarrel is not with the judicially noticeable facts, but with the inferences that arises from those facts: namely, that defendants reasonably concluded that Velac would be approved by the PDUFA date. Under *Tellabs*, the Court must consider those inferences and dismiss the complaint where (as here) it eviscerates any "cogent and compelling" inference of scienter. *See Vertex Pharms.*, 357 F. Supp. 2d at 352.

[4] Plaintiff summarily concludes that defendants could not reasonably rely on the approval of benzoyl peroxide and other drugs as indicative that Velac would be approved because those drugs are not "similar." Opp. RJN at 11. Yet, nowhere does plaintiff explain why these other topical treatments for acne were not similar. Nor does plaintiff allege that anyone – much less defendants – believed or was told that the FDA's approval of other topical treatments for acne with positive Tg.AC test results was not a positive indicia for Velac's approval. In short, plaintiff's assertions regarding the supposed differences between Velac and benzoyl peroxide are argument – not fact. As such, they must be disregarded when determining whether a plaintiff has alleged sufficient facts to state a claim. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986) ("Although for the purposes of this motion to dismiss we must take all the factual allegations in the complaint as true, we are not bound to accept as true a legal conclusion couched as a factual allegation."); *Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994) (same); *Western Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981) (same); *Lee v. Bender*, 2005 WL 1388968, at *7 (N.D. Cal. May 11, 2005) ("Plaintiff's opinions and legal arguments are not 'factual' allegations that may be considered by this Court.")

[5] BenzaClin, Duac, Differin and Retin-A, like Velac, are all topical treatments for acne. *See* Ex. 31, at 1; Ex. 33, at 1; Ex. 35, at 1; Ex. 36, at 1. Protopic is a topical treatment for atopic dermatitis, also known as eczema (Ex. 38, at 17); Aldara is a topical treatment for a variety of skin conditions including actinic keratosis and basal cell carcinoma (Ex. 40, at 45); and Clobex is a treatment for dermatosis (Ex. 43, at 1). Plaintiff wrongly argues that Differin is an oral treatment rather than a topical treatment. Like Velac, Differin is a "topical treatment" for "acne vulgaris." Ex. 35, at 1 (Differin Approval Letter).

IV. THE COURT SHOULD TAKE JUDICIAL NOTICE OF THE MOUSE STUDY ARTICLE

Plaintiff does not disagree that the Court can consider allegations in the earlier complaint in ruling on this motion to dismiss. Opp. RJN at 9-10; *see Azadpour v. Sun Microsystems*, Inc., 2007 WL 2141079, at *2 n.2 (N.D. Cal. July 23, 2007). Plaintiff argues, however, the Court should not take judicial notice of Exhibit 48 because the exhibit purportedly does not stand for the proposition for which defendants cite it, *i.e.* that the Tg.AC mouse model is "known to have a high rate of 'false positives.'" Opp. RJN at 10. However, the article states that ***the Tg.AC model in particular*** is more prone to showing a positive response for human ***noncarcinogens*** than the other transgenic mouse models and that:

> ***[T]ransgenic models also have actual or potential limitations*** for use in a carcinogen identification effort. For example, many current transgenic models…have mutations in only one pathway that ***may, or may not, be relevant to human cancer processes*** for a given chemical. In addition, the specific gene defect may influence tumor development and type, increasing the ***difficulty of modeling the human response***.

Ex. 48, at 5 (emphasis added). The article concludes that there are "important issues of validation and standardization [that] need further attention to permit their regulatory acceptance and use in human risk assessment." *Id.*, at 3. Because the article was alleged in the earlier complaint, the Court may consider it in ruling on this motion to dismiss. *Azadpour*, 2007 WL 2141079, at *2 n.2.

V. THE COURT SHOULD TAKE JUDICIAL NOTICE OF THE SUMMARY EXHIBITS

Plaintiff also objects to Exhibits 49 and 50. These are summaries of what plaintiff acknowledges are judicially noticeable facts. Such summaries are offered merely as a convenience to the Court, and the Court may properly consider them. *See, e.g.*, *DeMarco*, 149 F. Supp. 2d at 1218 (taking judicial notice of chart summarizing company's risk disclosures); *see also* Fed. R. Evid. 1006.

Exhibit 49 is a table summarizing defendants' stock sales and holdings of Connetics stock during the period of July 1, 2001 to July 9, 2006. It is based on judicially noticeable documents,

principally Forms 4, filed by the individual Connetics defendants (and to which plaintiff has no objection). *See* Exs. 21-24. Plaintiff does not contest the accuracy of Exhibit 49, but rather takes issue with its relevance, arguing that it is improper to include underwater options in calculating the defendants' holdings. However, plaintiff cites no authority whatsoever for this proposition. Rather, the law is clear that when evaluating a defendant's stock sales, a court must compare those sales to the defendant's total stock holdings, which includes exercisable stock options. *Silicon Graphics*, 183 F.3d at 986-87. There is no basis in the case law to exclude so-called underwater stock options from that analysis. Moreover, plaintiff's proposed rule makes no sense. A defendant would have the same motivation to increase the share price (so that the options were no longer underwater) regardless. Exhibit 49 is properly considered because it is based on documents that plaintiff admits are judicially noticeable, and it is an accurate summary of these voluminous documents.

Exhibit 50 is a table summarizing some of the meaningful cautionary language related to Velac gel. It is based on judicially noticeable documents, namely public filings and statements. *See* Exs. 1, 3-10, 12, 15-16. Plaintiff's objection to this exhibit ignores that, with respect to forward-looking statements, the Reform Act explicitly provides that courts must examine the contents of public statements and the relevant cautionary language that applies to those statements. 15 U.S.C. § 78u-5(e). Moreover, with respect to oral statements during analyst calls, courts must examine the cautionary statements that are contained in written documents and SEC filings referenced during the analyst calls. 15 U.S.C. § 78u-5(c)(2). Exhibit 50 properly excerpts the relevant cautionary language so that the Court can readily evaluate plaintiff's allegation that defendants intentionally deceived investors about Velac's prospects for FDA approval. As shown in Exhibit 50, defendants never promised that Velac would be approved, but rather repeatedly warned that FDA approval was uncertain and may be denied.[6]

[6] Plaintiff does not challenge that the January 24, 2005 conference call transcript is the proper subject of judicial notice, but asserts that the authenticity of Exhibit 2 is in question. Opp. RJN at 15. Plaintiff provides the Thomson StreetEvents version of the transcript attached as Exhibit B to the declaration of David R. Stickney. The transcripts submitted by plaintiff and defendants are identical except for the attribution of some of the statements. Whether the Court considers plaintiff's or defendants' version of the transcript, the substance of what was said is the same.

VI. CONCLUSION

For the foregoing reasons, the Court should grant judicial notice of Exhibits 1-52 of the Declaration of Christopher J. Steskal.

Dated: July 18, 2008

FENWICK & WEST LLP

By: /s/ Christopher J. Steskal
Christopher J. Steskal

Attorneys for Defendants Connetics Corp., John L. Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas G. Wiggans